

# Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial

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## ABSTRACT

**Objective** To determine whether self monitoring, alone or with instruction in incorporating the results into self care, is more effective than usual care in improving glycaemic control in non-insulin treated patients with type 2 diabetes.

**Design** Three arm, open, parallel group randomised trial.

**Setting** 48 general practices in Oxfordshire and South Yorkshire.

**Participants** 453 patients with non-insulin treated type 2 diabetes (mean age 65.7 years) for a median duration of three years and a mean haemoglobin A<sub>1c</sub> level of 7.5%.

**Interventions** Standardised usual care with measurements of HbA<sub>1c</sub> every three months as the control group (n=152); blood glucose self monitoring with advice for patients to contact their doctor for interpretation of results, in addition to usual care (n=150); and blood glucose self monitoring with additional training of patients in interpretation and application of the results to enhance motivation and maintain adherence to a healthy lifestyle (n=151).

**Main outcome measure** HbA<sub>1c</sub> level measured at 12 months.

**Results** At 12 months the differences in HbA<sub>1c</sub> level between the three groups (adjusted for baseline HbA<sub>1c</sub> level) were not statistically significant (P=0.12). The difference in unadjusted mean change in HbA<sub>1c</sub> level from baseline to 12 months between the control and less intensive self monitoring groups was -0.14% (95% confidence interval -0.35% to 0.07%) and between the control and more intensive self monitoring groups was -0.17% (-0.37% to 0.03%).

**Conclusions** Evidence is not convincing of an effect of self monitoring blood glucose, with or without instruction in incorporating findings into self care, in improving glycaemic control compared with usual care in reasonably well controlled non-insulin treated patients with type 2 diabetes.

**Trial registration** Current Controlled Trials ISRCTN47464659.

## INTRODUCTION

Self monitoring of blood glucose for people with non-insulin treated diabetes may lead to improved

glycaemic control and is recommended. Evidence of effectiveness is, however, inconclusive.<sup>1-3</sup> We tested whether self monitoring of blood glucose, with or without instruction in incorporating findings into self care, can improve glycaemic control in patients with non-insulin treated diabetes.

## METHODS

The diabetes glycaemic education and monitoring (DiGEM) study recruited patients from general practices in Oxfordshire and South Yorkshire. We aimed to determine whether haemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels at 12 months were significantly different between patients with non-insulin treated type 2 diabetes receiving one of three interventions: usual care (controls), less intensive self monitoring, and more intensive self monitoring.

Patients were eligible if they had type 2 diabetes, were aged 25 or more at diagnosis, were managed with diet or oral hypoglycaemic agents alone, had an HbA<sub>1c</sub> level  $\geq 6.2\%$ , and were independent in activities of daily living.

## Outcome measures

The primary outcome was the HbA<sub>1c</sub> level at 12 months. Secondary outcomes were blood pressure, weight, total cholesterol level, ratio of total cholesterol to high density lipoprotein cholesterol, and body mass index.

We transcribed the frequency of glucose testing from patients' diaries. Episodes of hypoglycaemia were categorised as grades 2 (mild), 3 (moderate), or 4 (unconscious). Increases in hypoglycaemic drugs were defined as an increase in the dose or frequency prescribed, progression from one oral agent to combination oral therapy, or addition of insulin to treatment. We also collected personal and clinical data on duration of diabetes, diabetes related complications, and EuroQol (EQ-5D) score.<sup>4</sup>

## Randomisation and procedures

We used computerised randomisation with partial minimisation to balance three covariates at baseline:

duration of diabetes, HbA<sub>1c</sub> level, and current treatment.

We identified patients from lists held by the general practitioners. At the assessment visit, beliefs about diabetes were elicited.<sup>5</sup> The role of diet, physical activity, and drugs were discussed. The behaviour change techniques included goal setting and review of physical activity and eating patterns.<sup>6,7</sup> Goal setting and review were continued in subsequent visits. Baseline blood tests and clinical measurements were taken and questionnaires completed.

### Interventions

Patients were allocated to one of the three interventions, initiated at the visit after randomisation and continued at visits at one, three, six, and nine months.

Control patients received usual care, including the use of goal setting and review. They recorded self care goals and strategies for achieving them in a diary.

Patients allocated to the less intensive intervention used goal setting and review techniques. They were given a glucose meter to record three values daily on two days a week (one after fasting and two before, or two hours after, meals) and to aim for glucose levels of 4-6 mmol/l after fasting and before meals and 6-8 mmol/l after meals. They were not given information on interpreting the readings. They recorded identified goals, activity, and glucose results in a diary.

Patients allocated to the more intensive intervention used goal setting and review. They were given a glucose meter and training and support in timing, interpreting, and using the results to enhance motivation and maintain adherence to diet, physical activity, and treatment. They were encouraged to experiment with monitoring to explore the effect of activities on glucose levels and to reflect on abnormal values in an attempt to identify contributing factors. They recorded goals, activities, and glucose results in a diary.

**Changes in haemoglobin A<sub>1c</sub> levels, blood pressure, cholesterol levels, weight, and body mass index between baseline and one year in patients with non-insulin treated type 2 diabetes, by randomisation group. Values are means (standard deviations) unless stated otherwise**

Variable	Control group* (n=152)	Meter group, less intensive self monitoring (n=150)	Meter group, more intensive self monitoring (n=151)	P value for difference between groups†
<b>HbA<sub>1c</sub> (%):</b>				
Baseline	7.49 (1.09)	7.41 (1.02)	7.53 (1.12)	
Follow-up	7.49 (1.20)	7.28 (0.88)	7.36 (1.05)	0.12
Change	-0.00 (1.02)	-0.14 (0.82)	-0.17 (0.73)	
<b>Systolic blood pressure (mm Hg):</b>				
Baseline	140 (18)	141 (17)	137 (18)	
Follow-up	136 (18)	137 (17)	134 (17)	0.77
Change	-4 (14.)	-3 (16)	-3 (14)	
<b>Diastolic blood pressure (mm Hg):</b>				
Baseline	80 (10)	80 (10)	78 (10)	
Follow-up	77 (10)	78 (10)	76 (10)	0.67
Change	-3 (9)	-2 (9)	-2 (8)	
<b>Weight (kg):</b>				
Baseline	86.7 (18.9)	90.4 (18.9)	86.9 (16.4)	
Follow-up	86.4 (19.4)	89.9 (19.0)	86.1 (15.7)	0.37
Change	-0.3 (2.7)	-0.5 (2.6)	-0.8 (3.3)	
<b>Total cholesterol level (mmol/l):</b>				
Baseline	4.73 (1.02)	4.64 (1.11)	4.67 (1.07)	
Follow-up	4.56 (1.03)	4.42 (0.95)	4.28 (0.84)	0.010
Change	-0.16 (0.84)	-0.22 (0.93)	-0.40 (0.90)	
<b>Ratio of total cholesterol to high density lipoprotein cholesterol‡:</b>				
Baseline	4.33 (1.12)	4.40 (1.33)	4.48 (1.35)	
Follow-up	4.18 (1.12)	4.11 (1.17)	4.02 (1.17)	0.013
Change	-0.15 (0.72)	-0.29 (0.86)	-0.46 (0.91)	
<b>Body mass index:</b>				
Baseline	30.9 (6.1)	31.9 (6.2)	31.0 (5.3)	
Follow-up	30.8 (6.3)	31.8 (6.3)	30.7 (5.0)	0.41
Change	-0.1 (1.0)	-0.2 (0.9)	-0.3 (1.2)	

Change is measured as one year follow-up minus baseline values.

\*No use of blood glucose meter.

†Adjustment for baseline values.

‡Based on 414 participants with paired values (137/152, 136/150, 141/151).

Control patients had blood HbA<sub>1c</sub> levels measured two weeks before their visit and the result fed back to them. Blood glucose values were reviewed at the visit for those allocated to self monitoring. To explore success of goals and to set new ones patients in each arm received feedback on glycaemic control.

Additional measures to ensure adherence to the intervention protocols included self review of taped consultations by the research nurses and external review by a sociologist.

#### Statistical analysis

We carried out a single intention to treat analysis of the main trial end points using analysis of covariance to compare mean HbA<sub>1c</sub> levels at follow-up between the three groups, with baseline HbA<sub>1c</sub> level as a covariate. If data were unavailable we imputed values by carrying forward the last measurement. We specified that in the event of a statistically significant overall result, comparisons of the two self monitoring groups independently with the control group would be carried out using *t* tests. We used repeated measures analysis of variance to compare HbA<sub>1c</sub> levels between groups during the trial. We also estimated the intervention effect in prespecified subgroups defined at baseline as duration of diabetes (above or below median), current management (oral hypoglycaemic drugs or dietary management), health status (above or below median EQ-5D score), and presence or absence of diabetes related complications. We tested for effect modification using analysis of covariance.

A Kaplan-Meier plot was used to explore adherence to a minimal level of self monitoring, defined as at least 26 tests over three months; significance was assessed with a log rank test. The mean numbers of tests by patients carrying out at least 26 tests in each quarter are also reported, with differences between the self monitoring groups compared with a repeated measures analysis of variance.

#### RESULTS

Between January 2003 and December 2005, 453 patients with non-insulin treated type 2 diabetes from practices in Oxfordshire (n=24) and South Yorkshire were randomised to one of three interventions (see [bmj.com](#)): usual care (n=152); less intensive self monitoring, using a blood glucose meter with advice to contact doctor for interpretation of the results (n=150); and more intensive self monitoring, with a blood glucose meter and training in interpreting the results (n=151).

Baseline personal and clinical characteristics were well balanced between the groups (see [bmj.com](#)). The median (interquartile) duration of diabetes was 3.0 years (1.8-6.4 years), mean (SD) age was 65.7 (10.2) years, and mean (SD) level of haemoglobin A<sub>1c</sub> was 7.5% (1.1).

#### Outcome measures

At 12 months no difference was found in HbA<sub>1c</sub> levels between the groups after adjustment for baseline levels

(P=0.12; table). The mean difference in change in HbA<sub>1c</sub> levels from baseline to 12 months between the control group and less intensive intervention group (not adjusted for baseline) was -0.14% (95% confidence interval -0.35% to 0.07%) and between the control group and more intensive intervention group was -0.17% (-0.37% to 0.03%).

A significant difference was found in the change in total cholesterol levels between the three groups (P=0.010). The mean difference in change in total cholesterol levels from baseline to 12 months between the control group and less intensive intervention group (not adjusted for baseline) was -0.06 mmol/l (-0.26 to 0.14) and between the control group and more intensive intervention group was -0.23 (-0.43 to -0.04). No differences were found in the other secondary outcome measures (table). Within the prespecified subgroups no significant interactions were found with allocated group (see [bmj.com](#)).

#### Use of meter

Patients allocated to less intensive self monitoring were significantly more likely to persist with the meter than those allocated to more intensive self monitoring. Ninety nine (67%) of those receiving the less intensive intervention and 79 (52%) receiving the more intensive intervention continued with the meter at least twice a week during the study (P=0.012; see [bmj.com](#)). Among those who continued with a meter, the mean number of readings over 12 months was significantly higher among patients receiving the more intensive intervention compared with those receiving the less intensive intervention (P=0.022; see [bmj.com](#)).

#### Changes in hypoglycaemic and lipid lowering drugs

No differences were found between the groups in the proportions of patients prescribed an increase in hypoglycaemic drugs between baseline and 12 months: 45 (30%) patients in the control group compared with 43 (29%) in the less intensive intervention group and 48 (32%) in the more intensive intervention group. One patient in the control group, four in the less intensive intervention group, and five in the more intensive intervention group were using insulin therapy by 12 months. No differences were found between groups in the proportions of patients where statin treatment was increased or added to therapy. Overall, 17 (11%) patients in the control group, 11 (7%) in the less intensive intervention group, and 19 (13%) in the more intensive intervention group who were not taking a statin at baseline were taking one by 12 months.

#### DISCUSSION

No significant improvement in glycaemic control was found after 12 months in patients with non-insulin treated type 2 diabetes using self monitoring of blood glucose levels when compared with those not self monitoring. No evidence was found of a significantly different impact of self monitoring on glycaemic control when comparing subgroups of patients defined by

**WHAT IS ALREADY KNOWN ON THIS TOPIC**

Self monitoring of glucose for non-insulin treated patients with diabetes is costly but may improve glycaemic control. Although some observational studies have suggested benefits, the results of randomised trials have been inconclusive.

**WHAT THIS STUDY ADDS**

It is not necessary routinely to recommend self monitoring of blood glucose in reasonably well controlled patients with non-insulin treated type 2 diabetes.

duration of diabetes, therapy, diabetes related complications, and EQ-5D score. Also no evidence was found that more intensive compared with less intensive monitoring led to differences in glycaemic control.

In this study patients were independently randomised, with concealed allocation of measurement of the main outcome and a low loss to follow-up. Participants' diabetes was reasonably well controlled and although most were not using a meter a minority had experienced their use. These factors may have limited scope for further improvement in glycaemic control. However, the participants were representative of well controlled non-insulin treated patients with type 2 diabetes in the community who are the target group for recommendations of up to twice daily self monitoring and testing after meals.<sup>8,9</sup>

We provided a common structure for interventions, incorporating standardised good care in all arms within which nurses discussed glycaemic control, assessed either by HbA<sub>1c</sub> levels or self monitoring of glucose levels, and its role in setting and monitoring self care goals.<sup>10</sup> Recent guidelines have based recommendations for self monitoring of glucose levels on a theoretical potential to better self manage glycaemic control.<sup>11,12</sup> We incorporated such self monitoring into a framework that, based on psychological theory, should have optimised its effect. Careful specification, training, and monitoring of consultations ensured that the allocated interventions were delivered as planned.<sup>13</sup> Despite an intervention based on standards of best clinical practice and underpinned by psychological theory, we found no convincing evidence of an effect on glycaemic control.

Compared with earlier trials on blood glucose monitoring, recent ones have been carried out with meters that require less blood and simplified procedures for testing. Our findings support those of a recent small trial using standardised counselling for intervention and control groups. The trial reported a non-significant reduction in HbA<sub>1c</sub> levels of 0.2% in the intervention group.<sup>14</sup> Our findings, however, conflict with those of two of the largest trials of self monitoring of blood glucose to date. One reported a significant decrease in HbA<sub>1c</sub> level of 0.3% in the intervention compared with control group.<sup>15</sup> However, over 30% of participants were lost to follow-up, and missing values were not imputed. Also, initial specific training in use of a

meter was not matched by additional training for the control group, although all patients received dietary advice. A second trial reported a reduction in HbA<sub>1c</sub> level of 0.46% in the intervention compared with the control group. Standardised counselling supporting lifestyle modification was, however, provided only to the self monitoring group.<sup>16</sup>

Fewer people in our trial allocated to more intensive self monitoring compared with less intensive self monitoring continued testing. Patients with reasonably well controlled diabetes do not need active encouragement to use a meter. The increased recording of hypoglycaemia in the self monitoring arms may be a result of an increased awareness of low glucose levels from using the meter rather than a biochemical difference between groups. Although no improvement in glycaemic control was observed, a small but significant improvement was found in total cholesterol levels with self monitoring. This finding is consistent with an increased intensity of self management in these groups, possibly mediated through increased dietary adherence or through taking lipid lowering drugs more regularly.

Routine self monitoring of blood glucose for patients with reasonably well controlled non-insulin treated type 2 diabetes seems to offer, at best, small advantages; is not well accepted; and the cost, effort, and time involved in the procedures may be better directed to supporting other health related behaviours.

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**Competing interests:** None declared.

**Ethical approval:** This study was approved by the Oxfordshire Research Ethics Committee B (002.059).

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## Derivation and validation of QRISK, a new cardiovascular disease risk score for the United Kingdom: prospective open cohort study

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### ABSTRACT

**Objective** To derive a new cardiovascular disease risk score (QRISK) for the United Kingdom and to validate its performance against the established Framingham cardiovascular disease algorithm and a newly developed Scottish score (ASSIGN).

**Design** Prospective open cohort study using routinely collected data from general practice.

**Setting** UK practices contributing to the QRESEARCH database.

**Participants** The derivation cohort consisted of 1.28 million patients, aged 35-74 years, registered at 318 practices between 1 January 1995 and 1 April 2007 and who were free of diabetes and existing cardiovascular disease. The validation cohort consisted of 0.61 million patients from 160 practices.

**Main outcome measures** First recorded diagnosis of cardiovascular disease (incident diagnosis between 1 January 1995 and 1 April 2007): myocardial infarction, coronary heart disease, stroke, and transient ischaemic attacks. Risk factors were age, sex, smoking status, systolic blood pressure, ratio of total serum cholesterol to high density lipoprotein, body mass index, family history of coronary heart disease in first degree relative aged less than 60, area measure of deprivation, and existing treatment with antihypertensive agent.

**Results** A cardiovascular disease risk algorithm (QRISK) was developed in the derivation cohort. In the validation cohort the observed 10 year risk of a cardiovascular event was 6.60% (95% confidence interval 6.48% to 6.72%) in women and 9.28% (9.14% to 9.43%) in men. Overall the Framingham algorithm over-predicted cardiovascular disease risk at 10 years by 35%, ASSIGN by 36%, and QRISK by 0.4%. Measures of discrimination tended to be higher for QRISK than for the Framingham algorithm and it

was better calibrated to the UK population than either the Framingham or ASSIGN models. With QRISK 8.5% of patients aged 35-74 are at high risk ( $\geq 20\%$  risk over 10 years) compared with 13% when using the Framingham algorithm and 14% when using ASSIGN. With QRISK 34% of women and 73% of men aged 64-75 would be at high risk compared with 24% and 86% according to the Framingham algorithm. UK estimates for 2005 based on QRISK give 3.2 million patients aged 35-74 at high risk, with the Framingham algorithm predicting 4.7 million and ASSIGN 5.1 million. Overall, 53 668 patients in the validation dataset (9% of the total) would be reclassified from high to low risk or vice versa using QRISK compared with the Framingham algorithm.

**Conclusion** QRISK performed at least as well as the Framingham model for discrimination and was better calibrated to the UK population than either the Framingham model or ASSIGN. QRISK is likely to provide more appropriate risk estimates to help identify high risk patients on the basis of age, sex, and social deprivation. It is therefore likely to be a more equitable tool to inform management decisions and help ensure treatments are directed towards those most likely to benefit. It includes additional variables which improve risk estimates for patients with a positive family history or those on antihypertensive treatment. However, since the validation was performed in a similar population to the population from which the algorithm was derived, it potentially has a "home advantage." Further validation in other populations is therefore required.

### INTRODUCTION

Risk equations for cardiovascular disease derived from the American Framingham cohort study are the most

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